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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,493	09/28/2001	Joseph Luber	MCP-0274	5286

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,493	LUBER ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/28/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Remarks and Request for Extension of Time filed 06/28/04.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-8, 10 and 17-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Remon (WO 01/21155 A1).

Remon discloses a rapidly disintegrating tablet comprising an active agent and wax particles (page 10, lines 14-18; page 19, lines 10-21). The wax is a microcrystalline wax or a natural wax (page 11, line 7 through page 15, line 8). The composition further contains disintegrants, swellable materials as well as other fillers (page 15, line 9 - page 18, line 6). The average size of the wax particles is from 0.5 to 2.0 mm (page 18, lines 7-18). The actives are chosen from a wide variety of known pharmaceutical agents (page 19, line 22 - page 20, line 18). The composition also includes a film coating (page 21, line 4 - page 22, line 8). The tablets are produced by compression (page 23, lines 3-9). The tablets are rapid disintegration tablets (page 24, line 16 - page 25, line 1). Remon does not refer to the wax particles as powder. The Examiner refers to the Hawley s Condensed Chemical Dictionary, 12 Edition, 1993, pp.

960-61 as a reference of interest. The dictionary defines a powder as any solid, dry material of extremely small particle size. Being that most of the instant claims do not recite a particle size for the wax particles, the instant claims are deemed anticipated by Remon.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Remon. The teachings of Remon are discussed above. Remon does not expressly teach the same concentration of wax or active agent or the same particle size for the wax particles.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary concentrations and particles sizes in tablet formulations. It is the position of the Examiner that these are limitations that would be routinely determined by one of ordinary skill in the art, through minimal experimentation, as being suitable, absent the presentation of some unusual and/or unexpected results. The results must be those that accrue from the specific limitations.

One of ordinary skill in the ad would have been motivated to do this to prepare similar tablets with different active agents that achieve the same goal of rapid

disintegration. The type of active agent incorporated into the composition determines the concentration of active agent. The amount of active may also vary the amount of other components in the composition.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the ad at the time the invention was made.

Claims 1 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Remon in combination with Cuca et al. (US 5494681). The teachings Remon are discussed above. Remon does not expressly teach including an insert of a second active agent.

Cuca teaches that tablet formulations can comprise one or active agents (col. 3, line 57). At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a tablet formulation with one or more active agents incorporated into the composition.

One of ordinary skill in the art would have been motivated to do this to provide a composition that better delivers a therapeutic dose to the host to better combat the disease or condition being treated.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 06/28/04 have been fully considered but they are not persuasive.

Applicant argues that Remon does not teach an immediate release tablet as demo, and based on this, it appears that the Examiner may not appreciate the difference between an immediate release tablet meeting the USP dissolution specifications for immediate release tablets containing said active ingredient and disintegration as disclosed in Remon. Applicant further argues that just because tablet may rapidly disintegrate does not mean that the tablet is an immediate release tablet that meets the USP dissolution specifications for immediate release. Contrary to the applicant's argument, applicant's attention is called to page 24, line 23, Remon discloses a solid shaped article is useful for preparing an *immediate release* suspension. Accordingly, Remon does teach an immediate release dosage form.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant argues that Cuca does not close the gap between the disintegration disclosed in Remon and the dissolution requirements of the claimed subject matter. Because disintegration and dissolution are not the same and because there does not appear to be any suggestion by cited documents that would lead one of ordinary skill in

the art to formulate the claimed subject matter based on the current record in the captioned application, the rejection is improper and should be withdrawn. In response to the applicant's argument, as discussed above, Remon does disclose an immediate release formulation (see page 24, line 23). Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Accordingly, the dissolution requirements of the claimed subject matter are obvious over Remon in view of Cuca.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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